

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 07-554V

March 14, 2008

Not to be Published

CAROLYN K. HORNE, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, *

Respondent. *

Peter J. Sarda, Raleigh, NC, for petitioner.

Lisa A. Watts, Washington, DC, for respondent.

Tetanus vaccine; no
preponderant evidence
of vaccine injury

MILLMAN, Special Master

DECISION¹

On June 21, 2007, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that tetanus vaccine that she received on September

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

26, 2006 when she was 71 years old, with a history of hypertension, dyslipidemia, depression, obesity, anxiety, urinary tract infection, anemia, vitamin B12 deficiency, and spinal disk protrusion caused an adverse reaction resulting in amorphous symptoms which no doctor has diagnosed.

On March 13, 2008, during a telephonic conference call, petitioner's counsel requested that the undersigned rule on the record.

FACTS

Petitioner was born on July 22, 1935.

On January 29, 2003, she saw Dr. Alan G. Forshey of Newton Family Physicians to complain of anxiety, shaky episodes, and stress. She weighed 222 pounds. Med. recs. at Ex. 8, p. 169.

On March 27, 2003, she telephoned her doctor to complain of nervous leg syndrome. Med. recs. at Ex. 8, p. 168b.

On February 23, 2004, she was noted to have chronic anxiety. Med. recs. at Ex. 8, p. 167.

On January 17, 2005, she complained of being tired all the time and having a lot of pain in her right knee and leg. Med. recs. at Ex. 8, p. 165.

On March 2, 2005, petitioner had an MRI done of her lumbar spine which showed a left paracentral disk protrusion. She had mild annular bulges at other lumbar levels with disk dehydration. Med. recs. at Ex. 9, p. 198.

On January 31, 2005, petitioner complained of pain and discomfort in her left leg, mostly in her calf but also down her thigh, originating from her back. She had occasional numbness.

Her reflexes were 1+ and equal. The diagnosis was sciatica. She weighed 226 pounds. Med. recs. at Ex. 8, p. 164b.

On December 20, 2005, petitioner was noted to have hypertension, dyslipidemia, and depression. She weighed 210 pounds. Med. recs. at Ex. 1, p. 7.

On June 12, 2006, petitioner complained of anxiety. Med. recs. at Ex. 1, p. 12.

On Tuesday, September 26, 2006, petitioner saw Dr. Shannon M. Sherfey for a urinary tract infection and a follow-up of her chronic medical problems. Dr. Sherfey prescribed Cipro. Med. recs. at Ex. 2, pp. 22-23.

On September 29, 2006, at 8:14 a.m., petitioner telephoned her doctor and said she had come in on September 26th for a urinary tract infection, and was given Cipro and Pyridium. She had had a problem with nausea ever since starting the medications. She vomited on the night of September 28th and her body ached, but she had no fever. She was dizzy and nauseated that morning and could not get out of bed. Med. recs. at Ex. 2, p. 24.

On September 30, 2006, petitioner saw Dr. Alan G. Forshey and told him that she got a tetanus shot on Tuesday and had not felt good since. Her body ached and she had no energy. She had fevers and sweats and was generally not feeling well. She had persistent nausea and thought it was a reaction to either Cipro or Levaquin. She denied vomiting, diarrhea, cough, or burning at urination. She had a recent urinary tract infection. Med. recs. at Ex. 2, p. 26.

On October 4, 2006, petitioner saw Dr. Forshey, complaining of dizziness, urinary problems, and fatigue for one week. She had myalgia and weakness. Her blood pressure was 130/40. On neurological examination, she was alert and oriented. Her deep tendon reflexes, gait, and strength were normal. Med. recs. at Ex. 2, p. 27.

On October 11, 2006, petitioner saw Dr. Sherfey who noted a possible reaction to the tetanus vaccine. On neurological examination, petitioner had no focal deficits, a normal gait, 5 out of 5 strength in her upper and lower extremities, and deep tendon reflexes of 2 to 3. Dr. Sherfey also noted a probable reaction to the tetanus vaccine. Med. recs. at Ex. 2, p. 32.

On October 13, 2006, petitioner saw Dr. Ryan Conrad, a neurologist. She told him that on September 26th, she had a urinary tract infection and received tetanus vaccine. By late evening, she felt fluish and had severe full-body myalgias. Her temperature was 100.4°. She had strength of 4 out of 5 in her upper and lower extremities. She had gait ataxia. Her reflexes were 2+ throughout. She claimed a loss of appetite but had gained 10 pounds. She weighed 208 pounds. Her blood pressure was 168 over 90. Med. recs. at Ex. 3, pp. 73, 75.

From October 12-13, 2006, petitioner was at Frye Regional Medical Center where she was tested and found to have vitamin B12 deficiency, anemia, iron deficiency, myalgia, and hypertension. Med. recs. at Ex. 3, p. 76. Her EMG (electromyography) and nerve conduction study tests were normal. MRIs of her brain and cervical spine were normal. Dr. Conrad thought she might have myopathy or myelitis from the tetanus vaccine, but there was no evidence of it on EMG. Med. recs. at Ex. 3, p. 76. No evidence of myopathy, myositis, acute disseminated encephalomyelitis or other neurodegenerative process as a result of the tetanus vaccine showed up on the tests. *Id.* Some sural potential loss on the nerve studies was explainable by the vitamin B12 deficiency. Med. recs. at Ex. 3, pp. 76-77. Her motor studies were preserved. Med. recs. at Ex. 3, p. 77. There was no evidence of Guillain-Barré or other acute neuropathic process. *Id.* Dr. Conrad started petitioner on ferrous sulfate, and a B12 replacement monthly. Because of her constipation, Dr. Conrad recommended a colonoscopy. *Id.*

On October 23, 2006, petitioner saw Dr. Sherfey who noted that petitioner had no focal deficits. She had a normal gait but was a little unsteady, mild tenderness in her left inner thigh, and normal quadriceps strength. Med. recs. at Ex. 8, p. 137.

On October 25, 2006, Dr. Sherfey wrote a letter to petitioner telling her that she had low levels of B12 and iron. There was no evidence of myopathy, myositis, acute disseminated encephalomyelitis, Guillain-Barré syndrome, or other neurodegenerative process as a result of the tetanus vaccine. She recommended that petitioner see an infectious disease specialist at Wake Forest University Baptist Medical Center. Med. recs. at Ex. 8, p. 137.

On January 18, 2007, petitioner saw Dr. Forshey, complaining of aches all over, less mobility, and decreased activity. Med. recs. at Ex. 8, p. 135.

On March 29, 2007, petitioner gave a history that she had recently been hospitalized for myocardial infarction. Med. recs. at Ex 8, p. 134.

On April 22, 2007, she gave a history that she had aches and community-acquired pneumonia. Med. recs. at Ex. 8, p. 132.

On July 12, 2007, petitioner saw Dr. Forshey who noted she was alert and oriented. Her deep tendon reflexes, gait, and strength were normal. Med. recs. at Ex. 8, p. 128.

On September 6, 2006 (three months after petitioner filed her petition for compensation), petitioner saw Dr. Forshey, telling him that since the tetanus vaccination, she tired easily, had to rest once or twice daily, was more nervous, and worried more than she had the year previously. She said she had increased sensitivity in her right forearm. Her reflexes were 2 to 3 and equal bilaterally. She moved all extremities well. Med. recs. at Ex. 8, p. 127.

Other Submitted Material

On December 4, 2007, petitioner filed pages 214 and 215 which consist of a statement from physician's assistant Jessica Cain, who works at Neurology Associates, recounting petitioner's complaints, concluding that the "exact extent of the reaction to the tetanus shot was not determined..." (*id.* at 214) and a statement from Dr. Shannon Sherfey of Newton Family Physicians, dated November 12, 2007, which is a letter addressed to petitioner's counsel. Dr. Sherfey states that petitioner complained of generalized weakness and severe myalgias, but all her testing was negative and her symptoms improved except for her complaint of continued arm heaviness. Petitioner saw Dr. Robert Sheretz, an infectious disease specialist at Wake Forest University Baptist Medical Center, who opined that a vaccine reaction was possible. Dr. Sherfey concludes that "there is a good chance" that petitioner had a vaccine reaction "but there is no way to prove a cause and effect relationship." *Id.* at 215.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]" the logical sequence being supported by "reputable medical or scientific explanation[.]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for tetanus vaccine, she would not have had whatever she had, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In the instant action, petitioner has not produced an expert report that establishes what illness she has and that the vaccine probably caused it. The most Dr. Sherfey and Dr. Sheretz state on page 215 is that there is a possibility. A preponderance of the evidence means that petitioner's expert must state that the vaccine probably caused her illness, whatever it is. Dr. Sherfey's stating there was a good chance of a reaction, but no way to prove a cause and effect relationship does not satisfy petitioner's burden, as the undersigned explained to petitioner's counsel during the status conferences of January 23, 2008 and March 13, 2008.

That Dr. Sherfey stated in the medical records in 2006 that petitioner had a probable vaccine reaction is nullified by her letter to petitioner's counsel in 2007 that there was merely a good chance of a reaction but no way to prove a cause and effect relationship. Proving a cause and effect relationship is exactly petitioner's burden here.

The undersigned gave petitioner's counsel time to go back to Dr. Sherfey and obtain a statement that would convey probability rather than possibility and also give a basis for Dr. Sherfey's opinion, assuming petitioner's counsel could obtain such an opinion from her or from some other medical doctor.

During the March 13, 2008 telephonic status conference, after the undersigned explained the deficiencies in petitioner's proof (lack of a medical opinion of probability rather than possibility, and no basis given for even that) together with petitioner's long series of chronic illnesses, all of which could explain complaints of weakness (even though her strength tested normal repeatedly), petitioner's counsel asked the undersigned to rule on the record. The undersigned takes this statement as an admission that petitioner cannot prove a prima facie case of causation in fact, and this petition must be dismissed.

CONCLUSION

This petition must be dismissed. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.²

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.